#### REMARKS

# Discussion of the Amendment

Claims 1, 2 and 4-31 are active. Claim 1 has been amended to further distinguish the ratio of B: A (now more than 11.67: 1) from the less than 10: 1 ratio of Yu et al. Support for this amended is found in the preferred ratios of these components disclosed in the specification on page 7, line 9, and page 9, line 1. These sections of the disclosure disclose the ratio of 70 wt.% B: 6 wt.% A and represent the upper ends of the preferred wt.% ranges of A and B (70 wt/%/6 wt.% = 11.67). Support for this ratio is also found in Examples 1, 6, 11-14, 18, 19, 21, 25 and 26. Minor revisions have been made to Claims 30 and 31. In view of the nature of these revisions, the Applicants do not believe that any new matter has been added.

# Content of the November 3, 2004 Discussion

The Applicants thank Examiners Yu and Padmanabhan or the helpful and courteous discussion of November 3, 2004. The examiners indicated that the ratio of "B is more than 10 based on 1 of the component A" did not adequately distinguish the emulsions from those of Yu, which refer to emulsions having a ratio of B:A of less than 10:1, e.g., emulsions having a B:A ratio of 9.999:1, 10:1 and 10.0001:1 would all be expected to be equivalents. It was suggested that Applicant might further distinguish the claimed emulsions from those of Yu by increasing the ratio of B:A recited by Claim 1, if support could be pointed out in the specification for the higher ratio. Amendments to Claims 30 and 31 to address the rejections under §112 were also discussed. The Applicants have now amended the claims as discussed

above and respectfully request favorable consideration of this response in view of these amendments.

#### <u>Information Disclosure Statement</u>

Applicants kindly request that the Examiner acknowledge consideration of the references cited in the Information Disclosure Statement filed December 4, 2003.

# Rejection—35 U.S.C. 112, second paragraph

Claims 30 and 31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is most in view of the amendments above.

#### Rejection--35 U.S.C. 103

Claims 1, 2, 6-8, 10-21, 27-29 and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over <u>Yu</u>, English translation of JP 63-126542. <u>Yu</u> does not render the present claims obvious because there is no disclosure or suggestion of a ratio of B:A of more than 11.67:1. The uppermost part of the ratio disclosed by <u>Yu</u> is "up to 10" parts oil to surfactant.

Moreover, Yu does not envisage or suggest selecting of a surface active agent having a dynamic surface tension of 57 mN/m or less for the production of an emulsion wherein the ratio of the oily component (B) is more than 11.67 based on 1 of the surface active agent (A).

Yu, see e.g. page 7, lines 1-3, is broadly directed to emulsions produced with various ratios of ingredients and does not suggest that stable, highly-transparent emulsions could be produced using a ratio of at least 10 parts oily component to 1 part of surface active agent.

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Specifically, <u>Yu</u> does not suggest that such emulsions could be produced by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less.

Moreover, Yu does not provide a reasonable expectation of success in obtaining emulsions with the superior properties of those of the invention, such as superior transparency. Selection of a surface active agent with a dynamic surface tension of 57 mN/m, provides an emulsion with superior properties, such as very high transparency, see Table A below.

TABLE A

surface active agent	dynamic surface tension	Transparency
lauroyl glutamate sodium	49.6 mN/m	>80%
POE lauryl ether	51.6 mN/m	>80%
N-lauroyl methyl taurine sodium	53.3 mN/m	>80%
lauryl Castor oil	58.0 mN/m	<20%
sorbitane monolaurlylate	58.4 mN/m	<20%

As shown in Table A above, oil-in-water emulsions produced using a surface active agent having a dynamic surface tension of 57 mN/m or less (bold text), produce highly

transparent emulsions, e.g. emulsions having a transparency above 80%. On the other hand, emulsions produced with surface active agents having a dynamic surface tension above 57 mN/m exhibited less than 20% transparency. Emulsions with high transparency are desirable in many applications, such as in cosmetics.

The Official Action indicated that the data in the Declaration were not persuasive because the data were not commensurate in scope with the claims. The Applicants disagree as the claims are clearly limited to emulsions produced by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less. The Declaration shows precisely this: that selection of a surface active agent having a dynamic surface tension of 57 mN/m or less produces a highly transparent emulsion as shown by a representative number of such surface active agents. The emulsions produced with the surface active agents required by the present invention each had transparency above 80%. On the other hand, comparative surface active agents not having a dynamic surface tension of 57 mN/m or less did not, producing emulsions having less than 20% transparency. Accordingly, the Applicants respectfully submit that the data of record clearly are commensurate in scope with the claims and demonstrate the superior properties of the emulsions of the present invention.

Therefore, as the prior art does not envisage or suggest the stable oil-in-water emulsions of the invention that use a surface active agent with a dynamic surface tension of 57 mN/m or less, or disclose or suggest the superior properties of such emulsions, the Applicants respectfully request that this rejection be withdrawn.

### Rejection--35 U.S.C. 103

Claims 4, 5 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of <u>Drapier et al.</u>, U.S. Patent No. 6,121,228. <u>Drapier</u> is directed to liquid cleaning compositions that contain less than 10 parts of oily substance to 1 part surfactant and <u>Draper</u> does not suggest producing emulsions by selecting a surface active agent having a dynamic surface tension of 57 mN/m or less. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

# Rejection--35 U.S.C. 103

Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Ansel, Pharmaceutical Dosage Forms and Drug Delivery Systems. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

#### Rejection--35 U.S.C. 103

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over <u>Yu</u>, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of <u>Gers-Berlag et al.</u>, U.S. Patent No. 5,876,702. The Applicants submit that this

rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

# Rejection--35 U.S.C. 103

Claims 23 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8 and 10-21 above, and further in view of Diec et al., U.S. Patent No. 6,468,551 B1. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

### Rejection--35 U.S.C. 103

Claims 24 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8, 10-21, 26 and 27 above, and further in view of Brunetta et al., U.S. Patent No. 5,562,911. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27.

#### Rejection--35 U.S.C. 103

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, English translation of JP 63-126542, as applied to Claims 1-4, 6-8, 10-21, 26 and 27 above, and further in view of Shiojima et al., U.S. Patent No. 6,066,316. The Applicants submit that this rejection may be withdrawn for the reasons set forth above for the rejection of Claims 1-4, 6-8, 10-21, 26 and 27. Moreover, Shiojima does not disclose an emulsion having an

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average particle size ranging from 0.01 to 0.2µm and is silent about the dynamic surface tension value of POE behenyl ether. Moreover, the rejection does not address the other components in the composition of Test Example 2, which appear to be surface active agents. The composition of Test Example 2 would not meet the weight ratio limitation of Claim 1 if these components are surface active agents.

### **CONCLUSION**

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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